HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Intraosseous Basivertebral Nerve Ablation Procedure (Intracept®)

Policy MP-068

Origination Date: 05/25/2021

Reviewed/Revised Date: 12/13/2023

Next Review Date: 12/13/2024

Current Effective Date: 02/13/2024

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Chronic low back pain (CLBP) is defined as persistent pain in the lumbar region lasting for more than 12 weeks. CLBP has many different causes. One suggested cause is vertebrogenic CLBP, which is thought to be associated with degeneration of the vertebral body or vertebral body endplates, which results in inflammation. The inflammatory response is perceived by the basivertebral nerve, a sensory nerve that enters the posterior vertebral body and branches out to the superior and inferior endplates. Pain signals are then transmitted to the central nervous system, causing vertebrogenic pain.

Basivertebral nerve ablation (BVNA), such as with the Intracept® System (Relievant Medsystems Inc.), is intended to relieve CLBP thought to be due to vertebrogenic causes by inhibiting the transmission of pain signals.

The Intracept® Procedure is a minimally invasive outpatient procedure that targets the basivertebral nerve (BVN) for relief of CLBP caused by vertebrogenic pain between L3 and S1. It consists of the Intracept Introducer Cannula, the Intracept Curved Cannula, the Intracept Radiofrequency Probe, and the Intracept Radiofrequency Generator. According to Relievant Medsystems Inc., the cannula is inserted via minimally invasive procedure under fluoroscopic guidance through the pedicle using a transpedicular approach. The procedure is performed under at least moderate conscious sedation. Fluoroscopic imaging is utilized to guide transpedicular positioning of the intervertebral instruments. After reaching the location of the

BVN trunk a flexible bipolar radiofrequency (RF) probe is inserted and then connected to a RF generator to heat the tip to 75-85 C for 7-15 minutes. This energy creates a 0.9-1.2 cm diameter spherical ablation zone. The procedure is repeated at each additional vertebral body identified pre-operatively. The minimally invasive procedure can be performed in the outpatient setting.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers intraosseous radiofrequency basivertebral nerve ablation (Intracept® procedure) *in limited circumstances* when the following criteria are met.

Coverage Criteria Requirements (Must meet ALL):

A. Skeletally mature with chronic (≥ 6 months) isolated lumbar back pain

B. Failure to respond to at least 6 months of nonsurgical conservative management, inclusive of routine NSAIDs or local steroid injections, formal physical therapy of at least 12 week duration and activity modification

C. Magnetic resonance imaging-demonstrated Modic Type 1 and/or 2 changes* (endplate changes, inflammation, edema, disruption, and/or fissuring) in at least 1 vertebral endplate at 1 or more levels from L3 to S1

D. Oswestry Index (ODI) score $\geq$ 30

E. Minimum of 4 on a 10 point NRS (Numerical Rating Scales) scale

F. No findings on advanced imaging to suggest a condition for surgery would resolve or if findings present, surgery is medically contraindicated.

G. Absence of Metabolic bone disease, spine fragility fracture history in which bone density has not been subsequently treated/corrected, lumbar trauma/compression fracture, or spinal cancer

H. BMI < 40

*Modic changes classification consists of 4 types:

- Type 0 - normal disc and vertebral body appearance
- Type I - presence of bone marrow edema within vertebral body and hyper-vascularization
- Type II - fatty replacements of the red bone marrow within vertebral body
- Type III - subchondral bone sclerosis

U of U Health Plans does NOT cover intraosseous radiofrequency basivertebral nerve ablation in the following circumstances:

A. MRI evidence of Modic changes at levels other than L3 to S1

B. Radicular pain (defined as nerve pain following a dermatomal distribution and that correlates with nerve compression in imaging)

C. Symptomatic spinal stenosis (defined as the presence of neurogenic claudication and confirmed by imaging)

D. Radiographic evidence of other low back pain (LBP) etiology

   i. Disc extrusion or protrusion > 5mm

   ii. Spondylolisthesis > 2mm at any level

   iii. Spondylolysis at any level

   iv. Facet arthrosis/effusion correlated with facet-mediated LBP

E. Bedbound or neurological condition that prevents early mobility

F. Spine infection or active systemic infection

G. Patients with severe cardiac or pulmonary compromise

H. Patients with implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety

I. Patients who are pregnant or lactating

J. Cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Radiofrequency ablation of intraosseous nerves is an emerging technology intended for treatment of chronic low back pain (CLBP). Researchers contend the nerves may be a source of intraosseous back pain and that interruption of the nerve pathway using radiofrequency will relieve the associated pain. It has been purported that the basivertebral nerve transmits pain signals from the vertebral body to the central nervous system. One device was cleared by the FDA 510(k) in 2016 for use in clinical settings, the INTRACEPT® System (Relievant MedSystems, Inc, Redwood City, CA) for use as a minimally invasive radiofrequency system for treatment of chronic lumbar back pain at one or more levels (i.e., L3 to S1),

when back pain is present despite at least six months of conservative care and is accompanied by either Type I or Type 2 Modic changes on MRI.

Evidence in the peer-reviewed scientific literature evaluating basivertebral nerve ablation consists of a pilot study, two RCTs (one comparing Intracept to sham treatment, one comparing Intracept to conservative treatment), retrospective and prospective case series. Fischgrund and colleagues published the results of three and twelve month outcomes from a RCT comparing Intracept (n=147) with sham treatment (n=78), as part of the FDA IDE trial (SMART Trial). Inclusion criteria consisted of chronic low back pain for at least six months, nonresponsive to at least six months of conservative treatment, and Modic type I or 2 changes at the vertebral endplate of the level targeted for treatment. Outcomes were measured at 2 and 6 weeks, and at 3, 6, 12, 18 and 24 months postoperative. At 12 months subjects randomized to the sham group were able to crossover to the treatment group. The authors noted due to a high crossover rate (57/78 subjects in the sham group crossed over at 12 months) the subjects treated with RF ablation acted as their own control for 24 month outcomes. ODI scores at three months demonstrated the treatment group had a 20.5 least squares mean improvement vs. 15.2 in the sham group. Using a 10 point improvement in ODI to define "clinically meaningful improvement" in the treatment group 75.6% were successful at 3 mos. and at 24 mos. 76.4% (81/106 subjects) were successful. The authors noted due to a high crossover rate the subjects treated with RF ablation acted as their own control for 24 month outcomes. The authors acknowledged a 17% per protocol patient fallout by month 24 (n=106). The results of these subjects at 24 months were compared to the overall treated population at baseline (n=128) and at 12 months to avoid unintentional bias. Clinical improvements in ODI, VAS, and the Medical Outcomes Trust Short Form Health Survey were statistically significant at all-time points during the two years. The mean percent improvements in ODI and VAS compared to baseline at two years were 53.7 and 52.9%, respectively. In the authors' opinion, RF ablation of the basivertebral nerve exhibited sustained clinical benefit in ODI and VAS scores for treatment of chronic low back pain. However, limitations of the trial include short term outcomes and a large placebo response to sham treatment causing conclusiveness to the authors' findings to be insufficient.

(Fischgrund, et al., 2018; Fischgrund, et al., 2019) Khalil et al. (2019) publish a second RCT comparing basivertebral nerve ablation to standard care for treatment of chronic low back pain. Inclusion criteria consisted of individuals with chronic pain, isolated to the back for at least 6 months, failure of 6 months of non-operative care, Type I or II Modic changes, and minimum ODI and VAS score of 30 and 4cm, respectively. Primary outcome measures included ODI at baseline, 3, 6, 9, and 12-months post procedure. A 10 point VAS for low back pain, ODI and VAS responder rates, SF-36, and EQ-5D-5L were used as secondary outcome measures. The primary endpoint was a between-arm comparison of the mean change in ODI from baseline to 3 months post-treatment. An interim analysis to determine superiority was conducted when at least 60% of the patients had completed the 3 month primary endpoint visit. Treatment of up to four vertebrae in nonconsecutive levels from L3 to S1 was allowed using the Intracept System; standard care treatment included but was not limited to acupuncture, chiropractic treatment, physical therapy exercise, and spinal injections. The authors reported that at the interim analysis at 3 months showed statistical superiority for all primary and secondary patient reported outcomes in the treatment group (n=51) compared with the standard care group (n=53). As a result, the study enrollment was halted and an early crossover was allowed to the control arm. Twenty-two total adverse events were reported; 15 were reported in 13 of the subjects treated with ablation, seven were procedure related and resulted in back pain of a new location, and either leg pain or paresthesia. Again, limitations of the study included non-structured standard care among subjects, short term outcomes, and as noted by the authors, inability to generalize results due to the strict clinical criteria for chronic low back pain.

More recently, Fischgrund et al. (2020) published the five year results from the treatment arm of their multicenter, prospective RCT evaluating intraosseous basivertebral nerve ablation for chronic low back pain. (SMART Trial). Patient reported outcomes of ODI, VAS, post ablation treatments, and patient satisfaction were reported, mean change in ODI was the primary outcome. This study includes the outcomes of 117/133 subjects within the United States centers, 117 subjects were adjudicated as successful for targeting. Subjects in the global population from the original trial were not included. Only 100 subjects were available for final follow up. Long term results for ODI, VAS improvement and responder rates were statistically significant post treatment; ODI was reduced on average by 25.95 ± 18.54 ($p< 0.001$), VAS was 4.38 ± 2.35 ($p< 0.001$), and responder rate using a 15 point improvement in ODI for a successful response was 77% at 5 years following ablation ($p< 0.001$). Using a two point improvement in VAS for a successful response 88% reported a successful response ($p< 0.001$). Improvement in function and pain level seen at one and two years post treatment were sustained at five years and beyond. The authors also reported a 73% reduction in opioid use from baseline at five years, a 55% reduction in subjects who received an injection in the prior 12 months when compared to baseline, and that there were no patient reported complications. In addition to limitations of the initial trial (e.g., large placebo effect) limitations of this continued trial includes loss of the control group from the initial trial, lack of outcomes from the global population, and industry funding.

In 2020 (updated 2022) the International Society for the Advancement of Spine Surgery (ISASS) published a guideline "Intraosseous ablation of the basivertebral nerve for relief of chronic low back pain". Evidence reviewed by the authors included a pilot study, a case series, a multicenter, prospective, parallel RCT (INTRACEPT Study), and the FDA IDE trial (SMART Trial, [12 and 24 month outcomes]). ISASS concluded the technology is supported as a treatment option for a well-defined subset of patients with chronic low back pain. Patient selection criteria defined by ISASS include individuals with all of the following: 1) chronic low back pain for at least 6 months duration, 2) failure to respond to at least 6 months of nonsurgical management, 3) magnetic resonance imaging (MRI) demonstrated Modic 1 changes (MC1) or Modic 2 changes (MC2) in at least 1 vertebral endplate at 1 or more levels from L3 to S1. Within these guidelines however ISASS acknowledges limitations of the evidence include industry funding that may lead to bias, a limited number of studies, short term follow-up (24 months), and an unknown effect on the primary degenerative process.

Further evidence in the form of a post hoc analysis of the Fischgrund trial noted above (Markman, et al, 2019), and observational case series (Becker, et al., 2017; Kim, et al., 2018; Truumees, et al., 2019) have been published and tend to support reduction of opioid use and improvement in pain and function in the short-term. Additional randomized clinical trials evaluating the Intracept system are currently underway (ClinicalTrials.gov database). However, long-term outcomes from well-designed RCTs have yet to be published and patient selection criteria have not been firmly established. At this time, the evidence in the peer reviewed scientific literature remains insufficient to support long term safety and efficacy of RF ablation of the basivertebral nerve as a treatment for chronic back pain.

A 2021 systematic review (Conger et al.) published results on the effectiveness of using intraosseous basivertebral nerve ablation in patients with chronic low back pain and Modic changes. Of the 725 publications screened, seven publications with 321 participants were ultimately included. The reported 3-month success rate for ≥50% pain reduction ranged from 45% to 63%. Rates of functional improvement (≥10-point Oswestry Disability Index improvement threshold) ranged from 75% to 93%. For comparison to sham treatment, the relative risk of treatment success defined by ≥50% pain reduction and ≥10-point Oswestry Disability Index improvement was 1.25 (95% confidence interval [CI]: .88-1.77) and 1.38 (95% CI: 1.10-1.73), respectively. For comparison to continued standard care treatment the relative risk of treatment success defined by ≥50% pain reduction and ≥10-point Oswestry

Disability Index improvement was 4.16 (95% CI: 2.12-8.14) and 2.32 (95% CI: 1.52-3.55), respectively. There is moderate-quality evidence that suggests this procedure is effective in reducing pain and disability in patients with chronic low back pain who are selected based on type 1 or 2 Modic changes, among other inclusion and exclusion criteria used in the published literature to date. However, success of the procedure appears to be dependent on effective targeting of the basivertebral nerve. The authors concluded that further high-quality, large prospective studies, that are not industry funded, are needed to confirm these findings.

A 2023 meta-analysis (McCormick et.al.) published on 8/29/23 assessed the effectiveness and safety of intraosseous basivertebral nerve ablation (BVNA) for treating vertebrogenic pain. This retrospective review looked at low back pain-related healthcare utilization (LBPr-HU) following BVNA. LBPr-HU data were pooled from three prospective studies. LBPr-HU categories of interest included non-invasive conservative care, opioid utilization, lumbosacral spinal injection (LSI), lumbosacral radiofrequency ablation (LRFA), and lumbosacral spinal surgery. Pre- and post-BVNA LBPr-HU were compared at both one- and five-years using McNemar's test for proportions and paired t-tests for means. Two hundred forty-seven patients received BVNA and had one-year follow-up; 205 had long-term follow-up (mean of 5.3 +/- 1.33 years). Twenty-seven percent fewer participants initiated conservative care in the year post-BVNA compared to the year preceding BVNA ($p < 0.001$; 95%CI 19.8-34.5). Of 77/247 participants taking opioids at baseline, 40.3% and 61.7% fewer were taking them at one-year and 5.3 +/- 1.33 years post-BVNA, respectively ($p < 0.001$). Of participants receiving LSIs in the year preceding BVNA, 81.2% fewer received LSI(s) in the year post-BVNA ($p < 0.001$; 95%CI 70.7-90.7); a 76.4% reduction in LSIs was maintained through a mean of 5.3 +/- 1.33 years post-BVNA. LRFA rates were 1.6% at one-year post-BVNA and 8.3% at 5.3 +/- 1.33 years post-BVNA. Lumbar fusion surgery was 0.8% at one-year post-BVNA and 6.5% at 5.3 +/- 1.33 years post-BVNA. The analysis concluded that patient's utilization of back pain related healthcare resource utilization (e.g., opioids, LSIs, and LRFA) post BVNA, with vertebrogenic pain was substantially reduced through five years compared to baseline. The analysis also found lumbar fusion rates to be less than half the published value at five years in similar populations.

A Hayes Evolving Evidence Review published July 2020 noted minimal support in the clinical studies for the Intracept technology specifically the studies did not consistently or predominantly report clear benefits or advantages in patient-oriented outcomes compared with a comparison group, only 2 studies with a comparison group were identified and the studies were of generally poor or fair quality. This review noted no systematic reviews identified and also there was only weak support from clinical guidelines for this technology. Specifically, as it relates to guidelines, it noted the guideline promoted by International Society for the Advancement of Spine Surgery published guideline is primarily expert opinion and/or lacking a formal evidence evaluation process.

In a 2021 update to the Hayes evolving evidence review above, an updated review of the literature was completed. In this update search (June 23, 2021) 13 studies were reviewed and an additional 1 met inclusion criteria. Some of the records identified in the 2021 update were redundant with those identified in 2020; overlapping search dates were used to ensure no studies were missed due to indexing delays. In summary, the analysis of clinical studies and systematic reviews concluded there is minimal support for using the Intracept Intraosseous Nerve Ablation System for chronic low back pain (CLBP) thought to be of vertebrogenic origin. The report noted clinical studies consistently reported pain relief, improved function and quality of life, however, the studies were generally poor and fair in quality. In addition, only 2 studies were identified with comparison groups where 1 suggested advantages over standard care at up to 6 months follow up and the other did not find clear benefits over sham at 1 year. The 1 systematic review concluded that Intracept is associated with patient's benefits, however, individual studies have quality limitations and it included some studies not included in this report

because of poor to fair quality ratings. Furthermore, it was noted the lead author was affiliated with the manufacturer interjecting potential bias into the conclusions. This report also noted professional guidelines provide weak support for this technology. Only 1 guideline was identified as supportive of basivertebral nerve ablation, but does not endorse use of the Intracept system and is primarily expert opinion and/or lacks a formal evidence evaluation process.

In the Hayes 2022 update, 1 single-arm systematic review with meta-analysis was identified that superseded a previously included systematic review. An additional systematic literature scoping review, which discusses efficacy and safety of basivertebral nerve (BVN) ablation for CLBP, as well as biases and gaps in published studies, was identified and may be of interest to the reader but was not used to select a level of support. No guidelines were identified that provided specific recommendations for the Intracept System; however, there are numerous radiofrequency ablation (RFA) systems on the market and professional organizations are unlikely to specifically endorse any single device in this category. Two clinical practice guidelines and a policy statement addressing RFA for CLBP were identified from 2 organizations the Department of Veterans Affairs Department of Defense and ISASS. The purpose for the 2022 ISASS policy statement is unclear, however, it may have been intended as a supplement to the 2020 ISASS guideline statement.

In 2023 Hayes included the American Society of Pain and Neuroscience (ASPN) guidelines stating “The application of [BVNA] for patients suffering from [VLBP] is still in its early stages of adoption and integration into spine care pathways. … [BVNA] [has] Level A grade evidence with high certainty that the net benefit is substantial in appropriately selected individuals". Also from ASPN, BVNA received an A grade with high level of certainty and net benefit for refractory, chronic, axial LBP of vertebral origin.

In February 2023 the North American Spine Society (NASS) became the third professional society to recommend coverage of BVNA. The policy states, “Basivertebral Nerve Ablation is indicated for patients presenting with lower back pain, when: Patients have chronic lower back pain for at least 6 months, Patients have failed to adequately improve despite attempts at nonsurgical management, Patients have Type 1 or Type 2 Modic changes on MRI.” In response to this recommendation the American Association of Neurosurgeons and the American Congress of Neurological Surgeons took exception to the policy noting this indication is overly broad and would essentially encompass anyone with chronic low back pain — ranging from chronic lumbar strain to lumbar stenosis, degenerative scoliosis, facet arthroplasty and disc disease. Importantly, Modic changes can be seen on MRI scans in our aging population as an asymptomatic finding, as low back pain is a symptom and not a diagnosis. Given this, further workup should be pursued before undergoing any ablative procedure to elucidate the underlying cause of the pain. In addition, there should be clarity on what other specific management options should be provided before undergoing this procedure and for how long they should be attempted before the patient is deemed a candidate for basivertebral nerve ablation. The coverage policy states that this procedure is not indicated if “Radiographic evidence of another obvious etiology for the patient’s LBP.” This statement appears to be more of a disclaimer than a characterization of an exclusionary diagnosis. Such an overly broad comment will not address the unindicated use of this procedure. Other contraindications such as “Patients with severe cardiac or pulmonary compromise” and “Patients with implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants unless specific precautions are taken to maintain patient safety” appear related to using this technique rather than proper recommendations of how to best treat the patient. The coverage policy refers to basivertebral nerve ablation but does not specify a technique. The rationale discusses both percutaneous interosseous ablation and transforaminal epiduroscopic ablation methods. Are both of these methods endorsed by NASS for coverage under the same indications and exclusions? This coverage policy attempts to frame basivertebral nerve ablation as the procedure to perform on patients

with chronic low back pain akin to other symptom management of low back pain — such as nonsteroidal anti-inflammatory drugs or physical therapy — with little unbiased non-manufacturer-supported evidence to support it. We strongly believe that basivertebral nerve ablation should be addressed as any new technology, with clear indications for its use and continued clinical studies supporting its efficacy, while watching for any potential significant negative impact on patient safety and quality of care.

Applicable Coding

CPT Codes

64628 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral

64629 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

HCPCS Codes

No applicable codes

ICD-10 Codes

M47.816 Spondylosis without myelopathy or radiculopathy, lumbar region

M47.817 Spondylosis without myelopathy or radiculopathy, lumbosacral region

M51.36 Other intervertebral disc degeneration, lumbar

M51.37 Other intervertebral disc degeneration, lumbosacral

M54.50 Low back pain

M54.51 Vertebrogenic low back pain

ICD-10 Procedure Codes

Use of the following codes when specified as intraosseous basivertebral nerve ablation:

015B3ZZ Destruction of Lumbar Nerve, Percutaneous Approach

015B4ZZ Destruction of Lumbar Nerve, Percutaneous Endoscopic Approach

References:

1. Conger, A., et al. (2021). "The Effectiveness of Intraosseous Basivertebral Nerve Radiofrequency Neurotomy for the Treatment of Chronic Low Back Pain in Patients with Modic Changes: A Systematic Review." Pain Med **22**(5): 1039-1054.
2. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2018 May;27(5):1146-1156. Eur Spine J. 2018 May;27(5):1146-1156.
3. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: 2-Year Results From a Prospective Randomized Double-Blind Sham-Controlled Multicenter Study. Int J Spine Surg. 2019 Apr 30;13(2):110-119.
4. Fischgrund JS, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Epub, 2020 May 25.
5. Freburger JK, Holmes GM, Agans RP, et al. The rising prevalence of chronic low back pain. Arch Intern Med. 2009;169(3):251-258. Available at: https://doi.org/10.1001/archinternmed.2008.543. Accessed July 2, 2020.

6. Hayes, Inc. (2023) Evolving Evidence Review "Intracept Intraosseous Nerve Ablation System (Relievant Medsystems) for Treatment of Adults with Low Back Pain". Last updated: September 28, 2023. Accessed: November 2, 2023. Available at: https://evidence.hayesinc.com/report/eer.intraceptlbp4481
7. Khalil JG, Smuck M, Koreckij T, et al. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2019 Jun 20. pii: S1529- 9430(19)30800-9. (Article in Press 8/19/2019).
8. Kim HS, Adsul N, Yudoyono F, et al. Transforaminal Epiduroscopic Basivertebral Nerve Laser Ablation for Chronic Low Back Pain Associated with Modic Changes: A Preliminary Open-Label Study. Pain Res Manag. 2018 Aug 14;2018:6857983.
9. Koreckij T, Kreiner S, Khalil JG, Smuck M, Markman J, Garfin S; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-Month treatment arm results. N Am Spine Soc J. 2021 Oct 26;8:100089. doi: 10.1016/j.xnsj.2021.100089. PMID: 35141653; PMCID: PMC8820067.
10. Lorio, M., et al. (2020). "International Society for the Advancement of Spine Surgery Guideline-Intraosseous Ablation of the Basivertebral Nerve for the Relief of Chronic Low Back Pain." Int J Spine Surg 14(1): 18-25. Accessed May 25, 2021. Available at: http://www.ijssurgery.com/content/14/1/18
11. Markman JD, Rhyne AL, Sasso RC, et al. Association between opioid use and patient-reported outcomes in a randomized trial evaluating basivertebral nerve ablation for the relief of chronic low back pain. Neurosurgery. 2020;86(3):343-347.
12. McCormick, Z. L., T. Curtis, A. Cooper, M. Wheatley and M. Smuck (2023). "Low Back Pain-related Healthcare Utilization following Intraosseous Basivertebral Nerve Radiofrequency Ablation: A Pooled Analysis from Three Prospective Clinical Trials." Pain Med.
13. North American Spine Society (NASS). Basivertebral nerve ablation: defining appropriate coverage positions. North American Spine Society. 2023; spine.org
14. Schnapp W, Martiatu K, Delcroix GJ. Basivertebral nerve ablation for the treatment of chronic low back pain in a community practice setting: 6 Months follow-up. N Am Spine Soc J. 2023 Jan 29;14:100201. doi: 10.1016/j.xnsj.2023.100201. PMID: 36926532; PMCID: PMC10011817.
15. Smuck M, Khalil J, Barrette K, Hirsch JA, Kreiner S, Koreckij T, Garfin S, Mekhail N; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021 Aug;46(8):683-693. doi: 10.1136/rapm-2020-102259. Epub 2021 May 24. PMID: 34031220; PMCID: PMC8311085.
16. Stroink AR, Bambakidis NC, Kanter AS Letter to NASS Draft Model Coverage Policy on Basivertebral Nerve Ablation, https://www.cns.org/advocacy/legislative-affairs-detail/neurosurgery-comments-on-nass-draft-coverage-polic; 2022 June
17. Truumees E, Macadaeg K, Pena E., et al. A prospective, open-label, single-arm, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Eur Spine J. 2019 May 21.
18. UpToDate® (2023) "Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment" Topic last update: April 10, 2023. Literature Reviewed: May 2023. Available at: https://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-nonpharmacologic-and-pharmacologic-treatment
19. U.S. Food and Drug Administration. Intercept Intraosseous Nerve Ablation System. 510(k) approval K153272. Accessed May 25, 2021. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf15/k153272.pdf